

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Arthritis Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on August 16 and 17, 2001, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn, Whetstone and Walker Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact:* Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or e-mail reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On August 16, 2001, the committee will discuss the efficacy and safety of submission tracking number (STN) 103950 Kineret™ (anakinra), Amgen, Inc., for reduction in signs and symptoms of active rheumatoid arthritis. On August 17, 2001, the committee will discuss safety updates for Enbrel™ (etanercept), Immunex, and Remicade™ (infliximab), Centocor, for the treatment of rheumatoid arthritis.

*Procedure:* On August 16, 2001, from 8 a.m. to 5 p.m. and on August 17, 2001, from 10 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 10, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 10, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations:* On August 17, 2001, from 8 a.m. to 9:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

